Arent Fox

Health Care Counsel

2021 Stark & Anti-Kickback Statute Final Rules

Smart In
Your World

arentfox.com

Contents

Smart In Your World

From Workbench to Bedside, We Have You Covered

Our team operates at the forefront of regulatory compliance and related litigation. We focus on helping hospitals and health systems navigate complex regulatory matters, including fraud and abuse and other regulatory and reimbursement issues.

Douglas A. Grimm
Health Care Practice Leader, DC
202.857.6370
douglas.grimm@arentfox.com

Anne M. Murphy
Partner, BOS
617.973.6246
anne.murphy@arentfox.com

Diane Roldán
Partner, SF
415.805.7985
diane.roldan@arentfox.com

Jill A. Steinberg
Partner, NY
212.492.3305
jill.steinberg@arentfox.com

Rachel Hold-Weiss
Partner, NY
212.484.3999
rachel.hold-weiss@arentfox.com

Stephanie Trunk
Partner, DC
202.857.6171
stephanie.trunk@arentfox.com

Thomas E. Jeffry, Jr.
Partner, LA
213.443.7520
thomas.jeffry@arentfox.com

Candace C. Sandoval
Associate, LA
213.443.7670
candace.sandoval@arentfox.com

Michele L. Gipp
Associate, NY
212.457.5403
michele.gipp@arentfox.com

Erin E. Atkins
Senior Attorney, DC
202.828.3436
erin.atkins@arentfox.com

Hillary M. Stemple
Law Clerk, DC
202.350.3638
hillary.stemple@arentfox.com

Discount Safe Harbor Final Rule Released: OIG Seeks to Adopt Major Changes

Final Rule largely tracks prior proposal to make significant changes to the Discount Safe Harbor and other regulatory safe harbors to the Federal Anti-Kickback Statute.

The Department of Health and Human Services Office of Inspector General (OIG) released a Final Rule (the Final Rule) adopting significant changes to the Discount Safe Harbor to the Federal Anti-Kickback Statute (AKS), related to rebates paid by pharmaceutical manufacturers to Medicare Part D plans and their agent pharmacy benefit managers (PBMs) for formulary placement as well as administrative fees paid to PBMs. While the Final Rule has not yet been published in the Federal Register, an advance copy can be found **here**. The revisions to the Discount Safe Harbor and additions of new safe harbors to the AKS become effective January 1, 2022.

Arent Fox **previously analyzed** the proposed rule upon which the Final Rule is based.

Without significant deviation from its original proposal, the OIG has adopted three major changes to the existing regulatory safe harbors contained in 42 C.F.R. § 1001.952.

First, the Final Rule revises the Discount Safe Harbor to explicitly exclude discounts and rebates on drug utilization made available to Medicare Part D plan sponsors and their PBM agents from the definition of "discounts" which may receive protection from AKS exposure under the Discount Safe Harbor.

The Final Rule adds a brand new exception to the definition of otherwise prohibited remuneration at 42 C.F.R. 1001.952(cc) to permit certain reductions in prices charged to Medicare Part D plan sponsors and Medicaid Managed Care Organizations (and PBMs acting under contract with either type of organization), so long as: (i) the reduced price is set in advance, in writing; (ii) the reduction in price does not involve a rebate unless its full value is provided to the dispensing pharmacy by the manufacturer, directly or indirectly, through a point-of-sale chargeback or series of point-of-sale chargebacks, or is required by law; and (iii) the reduction in price is completely reflected in the price of the prescription pharmaceutical product at the time the pharmacy dispenses it to the beneficiary. The Final Rule refers to this new exception as the "point-of-sale reductions in price for prescription pharmaceutical products" safe harbor (the point-of-sale safe harbor).

Finally, the Final Rule adds another new exception at 42 C.F.R. 1001.952(dd) to exclude certain service fees that pharmaceutical manufacturers may pay to PBMs from the definition of otherwise prohibited remuneration, as long as certain conditions are met. In order to meet the service fee exception, (i) the PBM must have a written agreement with the pharmaceutical manufacturer that specifies all of the services to be provided by the PBM; (ii) the services performed for such fees do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; (iii) the fees paid by the manufacturer to the PBM must be consistent with fair market value and must be a fixed amount (not based on a percentage of sales); and (iv) the fees must not take into account the volume or value of any referrals or business generated between the parties that could be paid for by Medicare, Medicaid, or other Federal health care programs. In addition, the PBM must disclose the services that it provides to every pharmaceutical manufacturer to each health plan with which it contracts on an annual basis, and to HHS upon request. The Final Rule refers to this as the "PBM service fees" safe harbor.

Of note, the Final Rule does not prohibit conditioning the point-of-sale deductions on formulary placement or conditioning

The health insurance industry opposed the changes in the proposed rule arguing that the replacement of AKS protection for formulary rebates paid to Medicare Part D plans and their PBM agents with the point-of-sale safe harbor would result in increased Medicare Part D premiums. However, nothing in the Final Rule addresses this concern. As the Final Rule does not take effect until January 1, 2022, there is plenty of time for stakeholders to consider a potential legal challenge and/or the new Biden Administration to further delay implementation of the Final Rule.


100X/1.
160/
NA 1.25

New Stark Law and Anti-Kickback Reforms Aimed at Value-Based Care

OIG and CMS, through a coordinated effort, have issued sweeping and much-anticipated final changes to the Anti-kickback and Stark rules. These changes are generally industry-friendly.

Introduction

On November 20, 2020, the Department of Health and Human Services (HHS), through a coordinated effort between the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG), publicly released final rules that overhaul the regulations governing the federal Physician Self-Referral Law (Stark Law) and Anti-Kickback Statute (AKS), as well as the Civil Monetary Penalty (CMP) Law. These rules were formally published in the Federal Register on December 2, 2020. The rulemaking is unusually lengthy, in large measure due to the extensive commentary and agency responses from many stakeholders who weighed in on the proposed rules that were issued in October 2019.

While the rules provide broad updates and revisions to both the Stark and AKS regulatory schemes, a central focus is to facilitate value-based arrangements in health care delivery. This is reflected in new exceptions and safe harbors that are specific to value-based activities and arrangements.

Billed by HHS as part of the "Regulatory Sprint to Coordinated Care," the rules were developed by CMS and OIG in an effort to **"advance the transition to a value-based healthcare delivery and payment system...."** As stated by OIG, the rules are intended **"to reduce the regulatory barriers to care coordination and accelerate the transformation of the health care system into one that better pays for value and promotes care coordination."**

Although CMS and OIG coordinated their rulemaking efforts, it is important to recognize that the rules contain meaningful differences. As stated in the extensive commentary to both rules, this divergence is driven by the inherent differences in the underlying statutes. The exceptions to the Stark Law are somewhat broader, but also are governed by a strict liability civil statute that requires strict adherence to the elements of each exception. In contrast, the safe harbors set forth in the OIG rules reflect the intent-based criminal AKS. The OIG rules are somewhat narrower than the CMS rules, in an effort described by both agencies as a "backstop" to abusive arrangements that may meet the technical requirements of the Stark rules. However, OIG points out that failure to adhere to every element in an OIG safe harbor does not necessarily mean that the AKS has been violated; rather, each arrangement will be evaluated in totality on a case-by-case basis to evaluate intent.

It also must be noted that there is **some measure of uncertainty** as to the effective date of many of the rules, and whether the incoming Biden administration will try to delay or suspend them. While this bears close monitoring over upcoming months, health care organizations are well-advised to digest the final rules on the assumption that many of the key provisions—especially those relating to value-based arrangements—may well stand.

The Value-Based Regulatory Framework

In broad terms, both CMS and OIG have adopted value-based exceptions and safe harbors that are tiered based on the degree of risk assumed by the "value-based enterprise" (VBE): (1) full financial risk; (2) "substantial" or "meaningful" downside financial risk; or (3) other value-based arrangements not rising to the level of full, substantial or meaningful risk. Generally speaking, the greater the risk assumed by the VBE, the broader the exception or safe harbor latitude.

OIG Rules: AKS Safe Harbors. OIG issued three new safe harbors for value-based arrangements, each tied to the level of risk assumed by the VBE and, potentially, a VBE participant:

— ***Value-based arrangements where the VBE assumes full financial risk.*** Generally protects monetary or in-kind remuneration between VBE and VBE participants, provided the VBE is at full risk

for all health care items, supplies, devices, and services, on a prospective basis for at least a year with a payer for each patient in the target patient population, through a written value-based arrangement that specifies all material terms.

— ***Value-based arrangement with substantial downside financial risk.*** Generally protects monetary or in-kind remuneration between VBE and VBE participants, provided the VBE assumes "substantial downside risk" from a payer, and each VBE participant assumes a "meaningful share" of the VBE's total risk, as those terms are described in the rules, on a prospective basis for at least a year, through a written value-based arrangement that specifies all material terms. The assumption of risk provisions appears to require that the VBE assume either 20% or 30% of any downside loss, depending on how that loss is calculated, and that the VBE participant assumes the 2-sided risk for at least 5% of the losses and savings, as applicable.

— ***Care coordination arrangements to improve quality, health outcomes, and efficiency.*** Generally protects in-kind remuneration only, exchanged between a VBE and VBE participants, or among VBE participants, if it is used predominantly to engage in value-based activities directly connected to coordination and management of care for the target patient population and does not result in more than incidental benefits for persons outside that target population. The arrangement must be set forth in writing and contain enumerated terms, and must be commercially reasonable, taking into account the arrangement itself and all value-based arrangements within the VBE. The recipient must pay at least 15 percent of the offeror's cost or fair market value for the in-kind remuneration.

Defined Terms. It is important to recognize that the OIG rules depend heavily on defined terms, including "value-based activity," "value-based arrangement," "VBE," "VBE participant," and "value-based purpose," among others. While "value" is not defined, "value-based purpose" is, and broadly includes: coordinating or managing the care of a "target patient population"; improving the quality of care for a target patient population; appropriately reducing the costs to or growth in expenditures without reducing the quality of care for a patient population, or transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a target patient population.

Entities Excluded from New Value-Based Safe Harbor Protection. Notably, the protections of these new safe harbors and the other OIG-issued safe harbors discussed in this alert are generally not available to certain entities (although these entities may be VBE participants):

— Pharmaceutical manufacturers, distributors, and wholesalers;

— Pharmacy benefit managers;

— Laboratory companies;

— Companies that primarily compound drugs or primarily dispense compounded drugs;

— Manufacturers, distributors, or wholesalers of devices or medical supplies; and

— An entity or individual that sells or rents durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS), subject to certain exceptions

That said, there is a limited opportunity for "limited technology participants" to exchange digital health technology with a VBE or VBE participant under limited circumstances in connection with care coordination arrangements; these participants are defined to include certain manufacturers of devices or medical supplies and certain DMEPOS entities.

Additional Requirements of New Value-Based Safe Harbors. It is also important to acknowledge that there are elements of the three new value-based safe harbors that impose general mandates or restrictions on value-based activities. For example, they prohibit the use of remuneration to market items or services furnished by the VBE or a VBE participant to patients or for patient recruitment activities; protect the ability of VBE participants to make decisions in the best interests of patients; prohibit the inducement of medically unnecessary items or services, or induce the limitation of medically necessary items or services to any patient; and require ongoing monitoring, assessment and reporting of quality and coordination of care. Importantly, the value-based safe harbor protections do not extend to the offer or receipt of an ownership or investment interest in an entity or any distributions related to such ownership interests.

Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency *OIG* finalized a new safe harbor that excludes from the definition of prohibited "remuneration" a patient engagement tool or support provided by a VBE participant to a patient in the target patient population of a value-based arrangement if certain requirements are met. Among other things, the support must be in-kind and not include any cash or cash equivalent;

the tools or supports must have a direct connection to the coordination and management of care of the target patient population, and the retail value of the tools and supports furnished to a patient cannot exceed $500 annually (subject to a regulatory inflation factor). This safe harbor is subject to the entity exclusions listed above for the three value-based safe harbors.

Outcomes-Based Payments. OIG modified the existing safe harbor for personal services and management contracts by adding a provision that excludes from the definition of prohibited "remuneration" outcomes-based payments if the recipient achieves one or more legitimate outcomes measures that: (1) are selected based on clinical evidence or credible medical support, and (2) have benchmarks used to quantify improvements in quality of patient care and/or material cost efficiencies while maintaining or improving quality of care. Importantly, this safe harbor requires a written agreement of at least a year, a methodology for determining compensation over the term of the agreement that is set in advance, consistent with fair market value, commercial reasonableness, and various other constraints of the personal services safe harbor. Benchmarks and payments must be assessed periodically to assure they are at fair market value. The entities excluded from the value-based purchasing safe harbors are also excluded from this exception.

While not the focus of this client alert, it is significant that OIG has amended the personal services and management contracts safe harbor to provide greater flexibility for part-time arrangements by eliminating the mandate that the written agreement detail the exact schedule, length and charge for each service increment. Moreover, OIG has loosened the requirement for setting compensation in advance by requiring only that the "methodology" be set in advance, rather than the aggregate compensation itself. The amendments will have a significant positive impact on the number of health sector arrangements that fall within this safe harbor, whether related to value-based purchasing or not.

CMS-Sponsored Model Arrangements and CMS-Sponsored Model Patient Incentives. OIG added a new safe harbor that protects certain payment arrangements and patient incentives offered in connection with CMS care models pursuant to the CMS Innovation Center or the Medicare Shared Savings Program (MSSP). This is intended to supplement fraud and abuse waivers issued in connection with each discrete program.

ACO Beneficiary Incentive Program. OIG also added a new safe harbor that adopts a statutory allowance for certain ACOs participating in select two-sided risk models to make incentive payments to beneficiaries of up to $20 for receipt of medically necessary primary care services.

CMS Rules: Stark Exceptions. As is the case with the OIG AKS safe harbors, CMS has issued three new exceptions for value-based arrangements, stratified by the level of risk assumed:

Full Financial Risk. Applies to value-based arrangements among VBE participants in a VBE that has assumed full financial risk for the cost of all covered items and services for each patient in the target patient population for the entire term of the value-based arrangement. The final rule, as compared with the proposed rule, expands the permitted pre-risk period from 6 months to 12 months.

Meaningful Financial Risk. Applies to value-based arrangements in which a physician is at "meaningful downside financial risk" for the entire term of the value-based arrangement, which is defined to mean the physician is at risk for at least 10% of his or her total remuneration (the risk assumption can take various forms). The final rule makes a significant accommodation, by reducing the proposed rule's minimum risk assumption from 25%.

Value-Based Arrangements Regardless of Level of Risk Undertaken by VBE or VBE Participants. As is the case for the OIG safe harbor governing limited or no risk arrangements, this CMS safe harbor contains a number of limitations and requirements, including an affirmative requirement that the VBE periodically monitor and assess the effectiveness of the value-based arrangement, and take corrective action if deficiencies are found.

General Observations; Comparison of OIG and CMS Value-Based Provisions. In evaluating the new CMS value-based exceptions to Stark, and in comparing those exceptions to the new value-based OIG safe harbors, the following points should be considered:

- Through a new Stark exception, the tiered value-based exceptions can apply to indirect compensation arrangements, if certain requirements are met.
- Unlike OIG, CMS does not exclude any enumerated entities from value-based exception protection.
- CMS does not distinguish between monetary and in-kind remuneration in the value-based exceptions.
- The value-based CMS exceptions do not incorporate requirements that compensation be set in advance, be consistent with fair market value, or not take into account the volume or value of a physician's referrals or other business generated by the physician. A low or no risk arrangement must demonstrate that it is "commercially reasonable," pursuant to a definition that provides added flexibility.

— Unlike the OIG definition of "value-based purpose," CMS will not consider quality of care to fall within this definition unless there is a reduction in costs too, or reduced growth in expenditures of, the payer.

— As is the case with the OIG value-based safe harbors, the exceptions are not available for ownership arrangements.

— It is important to recognize that CMS modified a number of important definitions and Stark terms, in addition to introducing new definitions specific to value-based arrangements. While a detailed description is outside the scope of this client alert, these changes are significant, and in general provide industry with greater flexibility, around terms that include, for example, "fair market value" and "commercially reasonable."

Practical Takeaways

There is much to digest in the final OIG and CMS rules. For those involved in or considering value-based arrangements, the following points should be considered:

— As a general proposition, these rules changes are significant and are industry-friendly. As it relates to value-based arrangements, they provide new guidance that can help drive risk decisions and structuring details or modifications.

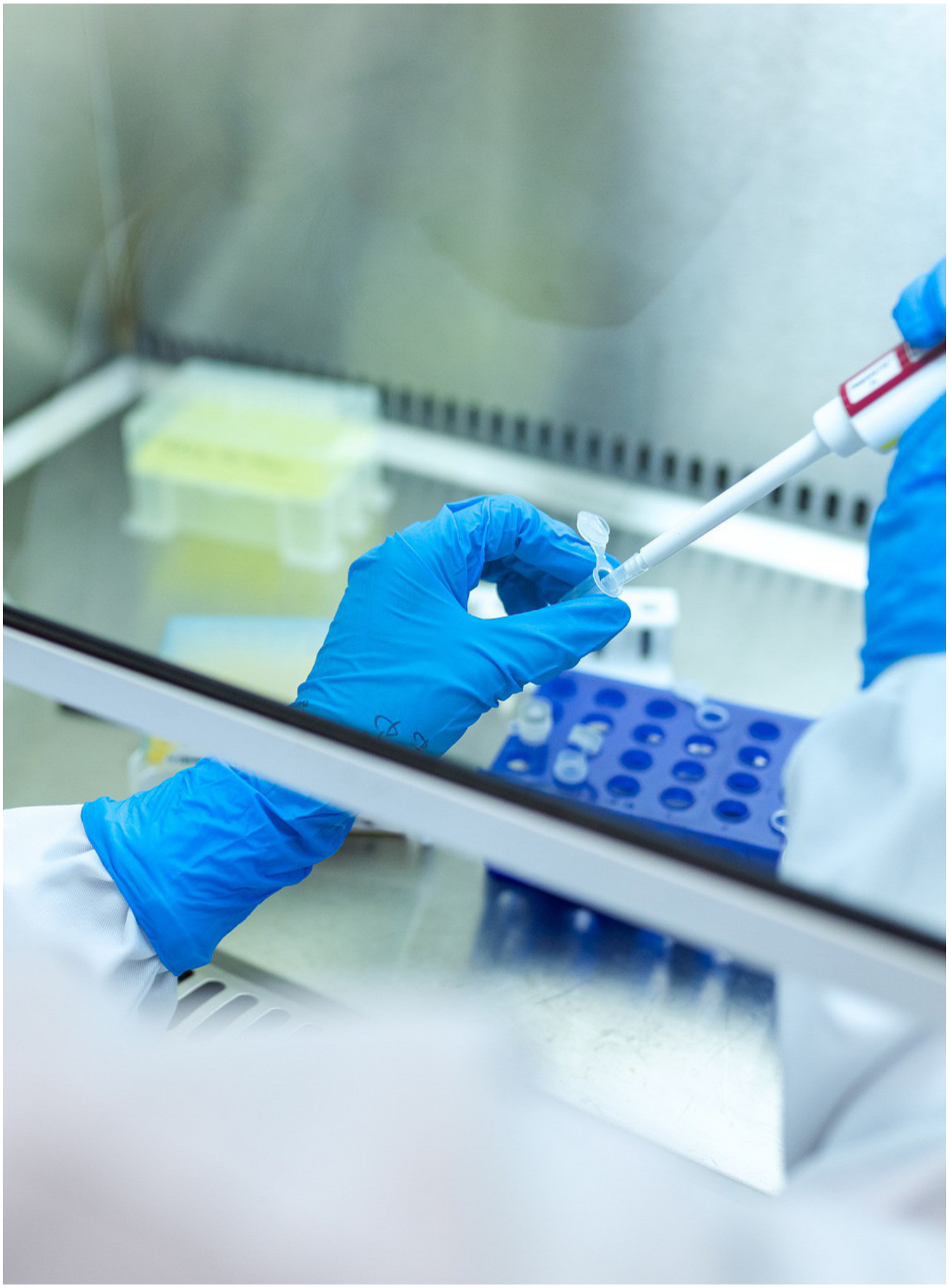
— While the rules were developed in coordination between CMS and OIG, there are significant differences in content and impact. As a result, many arrangements will need to be evaluated under both sets of rules and potential inconsistencies will need to be resolved.

— Remember that the OIG rules are generally more restrictive than the CMS rules. Failure to meet an OIG safe harbor, however, does not end the AKS analysis; a case-by-case assessment should be undertaken.

— Neither CMS nor OIG rules pertaining to value-based arrangements protect ownership relationships.

— In general, a value-based arrangement not only must meet regulatory requirements at the outset, but will need to be monitored and assessed on an ongoing basis to show continuing performance, with corrective action if deficiencies are identified.

— While there is some uncertainty as to the effective date of much of the rulemaking, and the consequent potential for the new administration to suspend and revisit it, there is a strong possibility that much or all of the rulemaking will stand.While this situation should be monitored closely, current or prospective participants in value-based arrangements are well-advised to allow for the strong possibility that these rules will remain largely intact.



Changes to Stark Law Definitions Impact Innovative Relationships and "Commercially Reasonable" Considerations

The Final Rule of the Stark Law revises the definitions of Fair Market Value and includes a definition of General Market Value to better align with actual practices without unduly restricting innovative relationships between physicians and entities providing designated health services.

Introduction

On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) published a final rule titled "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" (the Final Rule) which follows the proposed rules issued on October 9, 2019 (Proposed Rule). The Final Rule modifies the regulations for the Physician Self-Referral Law (Stark Law) in the Social Security Act (the Act). The Stark Law is a strict liability statute, and strict adherence to the elements of the applicable exception is required to be in compliance. CMS included changes to the Final Rule that revise existing definitions as well as added definitions to enable providers to comply more easily with the applicable exception requirements.

Many of the definitions contained in the Final Rule are terms that have also historically been utilized in other contexts, such as the Anti-Kickback Statute and in IRS guidance. As CMS has noted in prior commentary, as well as in the commentary to the Final Rule, the revisions and additions to the definitions in the Final Rule are only applicable to the Stark Law.

The three requirements applicable to many of the Stark Law exceptions are: compensation for the applicable arrangement must be at fair market value, the arrangements must be commercially reasonable, and no arrangement may take into account the volume or value of referrals (or other business generated) between the parties. One or more of each of these requirements is included in many of the Stark Law exceptions, and each of these requirements is an independent factor that, if applicable to the relevant exception, must be analyzed when the Stark Law is implicated. The revisions to the definitions, and the addition of new definitions, help clarify these different required elements.

Fair Market Value

The relationships contemplated by Stark and those that are included in the Stark exceptions contain a requirement that the payments or compensation for space, equipment, or services be at "fair market value." Fair market value is defined in the Act as "the value in arms-length transactions, consistent with the general market value." There are additional requirements for rentals or leases that "the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee." The Final Rule modifies the definition of "fair market value" generally, and more specifically, modifies the definition of fair market value applicable to the rental of equipment and rental of office space. This modification provides clarity to the statutory language.

The Final Rule defines fair market value as:

- Fair market value is generally defined as "the value in an arms-length transaction, consistent with the general market value of the subject transaction."
- Fair market value for rental of equipment is defined as "the value in an arms-length transaction of rental property for general commercial purposes (not taking into account its intended use), consistent with the general market value of the subject transaction."
- Fair market value for rental of office space is defined as "the value in an arm's-length transaction of rental property for general commercial purposes (not taking into account its intended use), without adjustment to

reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction."

In the commentary to the Final Rule, CMS provided additional insight noting that a determination of fair market value is usually the fair market price for completed bona fide sales of "assets of like type, quality and quantity in a particular market at the time of the acquisition" or compensation in bona fide service agreements with comparable terms at the time of the agreement," without taking into account any actual or anticipated volume or value of referrals. This explanation is consistent with prior commentary by CMS addressing fair market value.

It is important to note that when evaluating a potential relationship in which the Stark Law is a factor, the dollar amount of the fair market value is one of two components that must be reviewed. The compensation to be paid must be at fair market value (as defined in the Final Rule) **and** must also not take into account the volume or value of referrals (or volume or value of other business generated by the physician, if applicable). If either of those two components cannot be met, then the relationship would not be permissible under the Stark Law.

Many commenters to the Proposed Rule requested that CMS provide certain rebuttable presumptions or safe harbors for compensation as to what would be considered fair market value. In the Final Rule, CMS declined to include any such guidance, and noted that in all phases of the Stark Law, CMS has been consistent in its description of the determination of what would constitute the establishment of "fair market value" and "general market value." CMS has stated that it would "intend to accept any method that is commercially reasonable and provides [us] with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions that are not in a position to refer to one another."

General Market Value

Prior to the issuance of the Final Rule, the term "general market value" was included in the definition of "fair market value" of the Stark Law and was not separately defined. In the Proposed Rule, the definition of "general market value" was equated to "market value," a term utilized in valuation principles. However, based on numerous comments received to the Proposed Rule, CMS acknowledged that the use of the term "market value" did not achieve the objective in defining "general market value," and, therefore, the concept and term relating to "market value" is not included in the Final Rule. It is important to keep in mind that even though the concept of "market value" has been eliminated, the parties are obligated to consider the general market value of the transaction entered into by the parties without taking into account any other business arrangements between the parties.

Similar to the revised definitions of "fair market value," the Final Rule provides a general definition of "general market value," as well as general market value definitions applicable to specific types of arrangements.

The new definitions of general market value are:

- For Assets: With respect to the purchase of an asset, the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.

- For Compensation: With respect to compensation for services, the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.

- For Rental of Equipment or Office Space: With respect to the rental of equipment or the rental of office space, the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

Commercially Reasonable

Many of the exceptions to the Stark Law, including the exceptions for employment, personal services arrangements, leases, and timeshare arrangements include the term or concept that the relationship must be "commercially reasonable." However, prior to the issuance of the Final Rule, while the concept of an arrangement being "commercially reasonable" was addressed and discussed, the term "commercially reasonable" was not defined in the regulations. To provide clarification to the standard that an arrangement be "commercially reasonable," CMS has included a new definition of the term "commercially reasonable." An arrangement is considered to be "commercially reasonable" if "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."

In its commentary to the Final Rule, CMS stated that the determination as to whether an arrangement is "commercially reasonable" will depend on "whether the arrangement makes sense to accomplish the parties' goals," and such determination does not depend only on the compensation terms. While

compensation terms are an important component of the arrangement between the parties and the ability to accomplish the parties' goals, CMS recognizes that an arrangement may meet the commercially reasonable standard even if one or more of the parties does not benefit financially from the arrangement. This standard represents a notable change from the government's position in earlier Stark Law enforcement cases, including the ***Halifax* case**, where the government took the position that arrangements resulting in financial losses (*i.e.*, arrangements where a party did not benefit financially) could not be commercially reasonable

For value-based arrangements, the new exceptions contained in the Final Rule do not include a requirement that the value-based arrangement be commercially reasonable. For a comprehensive analysis of the new value-based arrangement requirements, please refer to the Arent Fox Alert, ***New Stark Law and Anti-Kickback Reforms Aimed at Value-Based Care***.

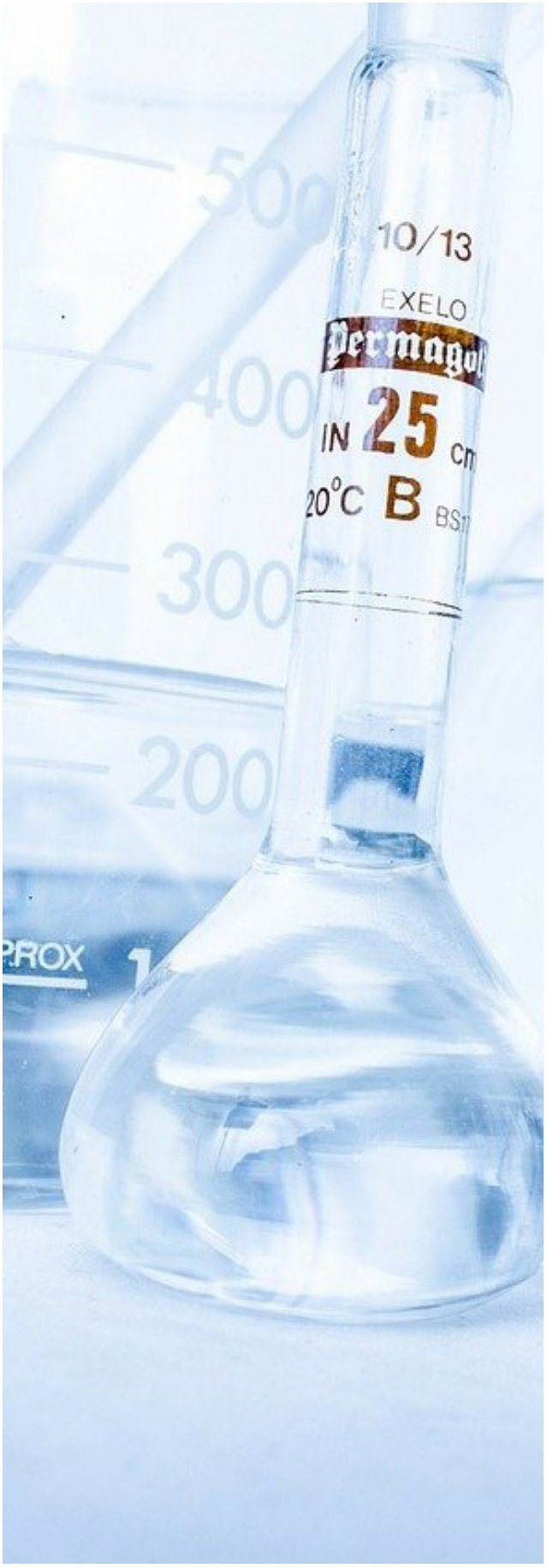
Practical Takeaways

The intent of the revisions to the Final Rule is to ease the regulatory burden for parties entering into arrangements where the Stark Law is implicated.

- Parties should review existing arrangements for compliance with the new commercial reasonableness definition, and ensure that the compensation paid is consistent with fair market value and general market value.

- Parties should review their existing arrangements to ensure compliance with the specified requirements with respect to compensation for space, equipment, or services, including that the compensation must not to take into account other business arrangements between the parties or the generation of referrals between the parties. If the specific arrangement is for space or equipment, there are additional considerations and requirements that must be met.

- Any future relationships entered into where the Stark Law is implicated must be compliant with the newly defined requirements, and any existing arrangements that are determined not to be compliant with the relevant exception will need to be modified to meet all of the applicable elements for that particular exception.



Revisions to Stark Law Rules Covering Physician Profit Sharing and Bonuses

Supporting CMS's Transition to a Value-Based Healthcare Delivery and Payment System.

The Centers for Medicare & Medicaid Services (CMS) published a Final Rule in the Federal Register on December 2, 2020, overhauling the regulations governing the federal Physician Self-Referral Law (Stark Law). These far-reaching changes and clarifications affect, among many other matters, profit sharing and productivity bonuses. Although other portions of the Final Rule go into effect January 1, 2021, the profit sharing and productivity bonus provisions do not go into effect until January 1, 2022.

Broadly, the Stark Law prohibits a physician from making a referral for designated health services (DHS) covered by Medicare to an entity with which the physician has a financial interest, including compensation and ownership or investment interests. There are, however, certain exceptions, including services provided by the physician or a member of the physician's group practice, provided certain criteria have been met. Moreover, a physician can be paid a share of overall profits of a group practice derived from the provision of DHS provided that the share is not related to the volume or value of referrals of DHS. A physician in a group practice can be paid a productivity bonus if the bonus is not related to the volume or value of referrals of DHS.

As noted in the Arent Fox Alert, ***New Stark Law and Anti-Kickback Reforms Aimed at Value-Based Care***, while the rules provide broad updates and revisions to the Stark regulatory schemes, a central focus is to facilitate value-based arrangements in health care delivery. This is reflected in a new provision under Stark for value-based activities and arrangements by physicians in group practices. The new provision allows a member of a group practice to receive profits from DHS directly attributable to the physician's participation in a value-based enterprise. CMS clearly has made the determination that participation in such enterprises is so essential that it is allowing a direct tie between a physician's participation and the profits derived from DHS.

CMS also made a number of what it considers non-substantive and clarifying changes to the rules regarding profit-sharing and productivity bonuses. Among other things, CMS clarified that if a group has five or fewer physicians, overall profits means the profits from DHS from the entire group; but if a group has more than five physicians, the group may designate a component of at least five physicians to aggregate the profits for the purpose of distribution.

As noted, the profit sharing and productivity bonus sections of the Stark Law do not go into effect until January 1, 2022. CMS is delaying the effective date to allow group practices to have time to adjust their compensation practices.


75mm X 200m
LOT NO :DPA1806
STEAM
WHEN CHEMI VAPOUR or
STEAM STERILISED

Searching for Safe Harbors? CMS-Sponsored Model Participants Receive Anti-Kickback Statute Protection

Enrolling in such a CMS-sponsored innovation model now has an added benefit: a new Anti-Kickback Statute (AKS) safe harbor.

In its mission to reward value over volume, the Centers for Medicare & Medicaid Services' (CMS) Innovation Center develops and tests novel payment and service delivery models for patient care. On November 20, 2020, the Office of Inspector General (OIG) **adopted regulations** creating two AKS safe harbors related to CMS-sponsored models (the New AKS Regulations) recognizing the importance of such models.

- The first safe harbor protects payments between CMS-sponsored model participants;
- The second protects patient incentive payments made pursuant to CMS-sponsored models.

Both safe harbors are found at Section 1001.952(ii) of the Code of Federal Regulations, Title 42.

CMS Innovation Models

As payers and providers transition from fee-for-service to value-based care, participation in Accountable Care Organizations (ACOs) continues to rise. According to Health Affairs, in 2019 there were over 1,500 public and private ACO contracts, covering nearly 44 million patients, reflecting a slow but steady increase over the past ten years. In addition to ACOs, CMS also tests new types of alternative payment models, including models for episode-based payment initiatives, primary care transformation, and initiatives focused on Medicaid and CHIP populations. CMS currently manages **45 different models** that are ongoing or accepting applications, and its Innovation Center continues to **develop new model varieties**, to ensure that different entities and clinicians can participate. CMS posts reports on its models' successes and setbacks each year **here**.

Existing Fraud and Abuse Waivers

To facilitate CMS's experimentation with new payment methods, Congress authorized the Secretary of Health and Human Services (HHS) to issue fraud and abuse waivers to model participants, pursuant to Section 1115A(d)(1) of the Social Security Act. OIG publishes waivers and guidance on using the waivers **here**. Depending on the model, these waivers permit participants to exchange payments that advance the model's goals or provide incentive payments to patients, which might otherwise risk AKS enforcement.

Although existing fraud and abuse waivers help protect model participants, they require HHS's affirmative intervention and the issuance of a waiver. The New AKS Regulations provide an additional safe harbor that model participants can use without needing a separate waiver.

New AKS Safe Harbors for Model Participants and Patient Incentives

Under two new safe harbors, the AKS does not apply to transactions "between or among CMS-sponsored model parties under a CMS-sponsored model arrangement," or to any "CMS-sponsored model patient incentive." During the comments phase, stakeholders expressed their hope that the new safe harbors would "encourage greater voluntary participation in new CMS-sponsored models" and result in "a simplified and standardized approach rather than disparate OIG waivers, with tailored conditions, for CMS-sponsored models."

Existing fraud and abuse waivers may still provide participants additional, specific benefits not found in the safe harbor. Fortunately, OIG assured participants that "[e]xisting model waivers will continue in effect in accordance with the waiver terms," and that "the promulgation of this safe harbor does not preclude OIG from issuing model-specific waivers in the future." OIG did caution, however, it would expect to issue fewer model-specific waivers going forward as participants increasingly rely on the safe harbors instead.

Safe Harbor Requirements and Conditions

The safe harbors apply only if CMS makes a determination that the model qualifies for the safe harbor. This requirement ensures that CMS still holds the reins and can determine, in its discretion, that certain models pose too great of a compliance risk to justify an AKS safe harbor.

Second, the safe harbors only apply to CMS-sponsored model participants and their agents. OIG considered comments from stakeholders requesting a broader safe harbor that would also protect other value-based arrangements, not sponsored by CMS. But OIG was convinced that the fraud and abuse risks were still too high. CMS models are highly regulated, monitored, and transparent. This level of oversight from CMS helps reduce fraud and abuse concerns, justifying the safe harbor exception.

Model participants that wish to use this new safe harbor for their transactions must confirm that their financial arrangement supports the CMS model's goals and the goals of the AKS to reduce fraud and abuse. Parties must document how their transactional arrangement advances the model's aims, including discouraging the provision of medically-unnecessary items or services. In addition, the parties must confirm that their financial arrangements are not intended to solicit or induce patient referrals or business, echoing the goals of the AKS.

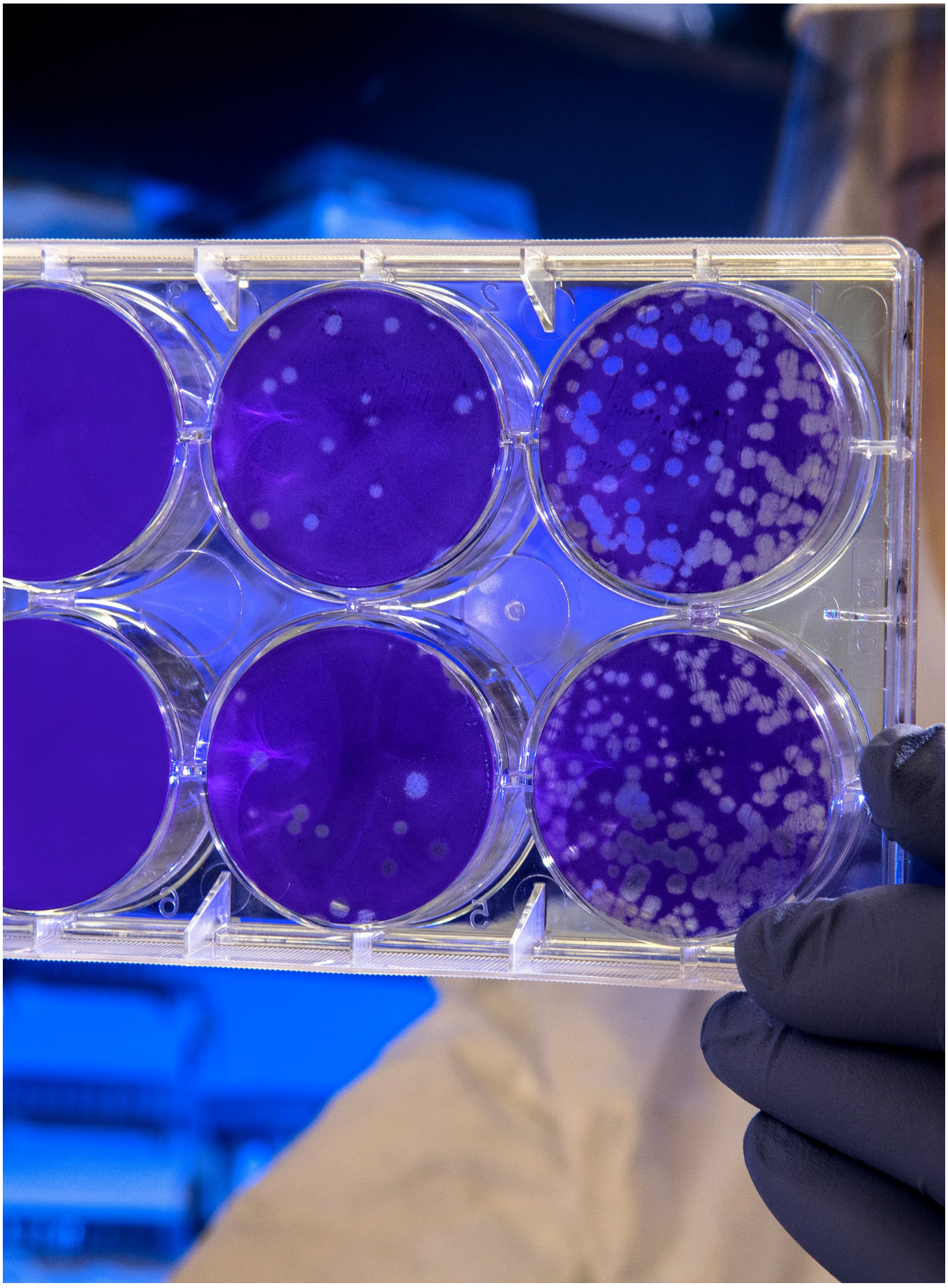
Patient Incentive Safe Harbor

The new safe harbor for patient incentives could spur further experimentation in rewards-based care. During the commenting phase, stakeholders urged OIG to protect a broad range of potential incentives, including for transportation, nutrition support, home monitoring technology, and gift cards. Commenters predicted that future models might experiment with forms of patient incentives that may not "directly" relate to health care, but that still encourage healthy habits or incentivize patients to seek health care. Commenters also sought flexibility on what types of patients could receive these incentive payments, and when.

In response, OIG confirmed that the new AKS safe harbor could potentially protect a broad range of incentives raised by commenters, depending on approval from CMS. In its draft rule, OIG initially required patient incentives to have "a direct connection to the patient's health care." In response to comments, the new safe harbor includes other types of incentives if "the participation documentation expressly specifies a different standard." The incentives may also be furnished not only by CMS model participants but also by other entities specified in the participation agreement. This language preserves CMS's flexibility. CMS has broad discretion to approve new and different patient incentives in its model participation agreements. These CMS participation agreements, in turn, determine what types of transactions will receive safe harbor protection. OIG's revisions reflect an ongoing policy choice to afford CMS as much flexibility as possible to design innovative payment systems in the future.

Going Forward

The decision of whether to participate, or continue participating, in CMS-sponsored model is a complex one, with many different benefits and drawbacks. OIG's New AKS Regulations now provide one additional benefit of participation: an AKS safe harbor. These regulations may help encourage participation in existing models and further innovation in future models.



Changes to the Stark Law's Special Rules on Compensation Create Flexibility and Reduce Confusion for Physicians and Other Health Care Providers

In its recent Final Rule significantly revising the federal Physician Self-Referral Law (Stark Law), the Centers for Medicare and Medicaid Services (CMS) implements several important changes to the special rules on compensation set forth in 42 C.F.R. § 411.354(d).

These include clarifying the phrase "set in advance," modifying the requirements for directed referrals, and providing an objective test for determining whether compensation takes into account the volume or value of referrals. Importantly, these changes reduce unnecessary regulatory burden on health care providers and suppliers, create flexibility for physicians and other health care providers to structure certain compensation arrangements, and reduce confusion, consistent with many other changes in the Final Rule. The changes, which were published in the Federal Register on December 2, 2020, go into effect on January 19, 2021.

Things to Know

- The set in advance provision for compensation for an initial arrangement is optional and the compensation does not have to be reduced to writing before the furnishing of the items or services.
- Parties may modify the terms of the compensation during the course of the arrangement provided that all terms of the applicable exception are met and the modified compensation is determined and reduced to writing before the items or services for which the modified compensation will be paid are furnished.
- For directed referrals, the physician's compensation may take into account the volume or value of referrals, but the existence of the compensation arrangement and the amount of the compensation may not be contingent on the number or value of the physician's referrals.
- Compensation to a physician takes into account the volume or value of referrals only if the formula used to calculate the compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the compensation that positively correlates with the number or value of the physician's referrals to the entity.

Compensation Set in Advance

Several exceptions under §§ 411.355 through 411.357 of the Stark Law require compensation to be set in advance to meet the terms of the exception. These exceptions include, without limitation, rental of office space or equipment, personal service arrangements, and fair market value compensation.

The Final Rule clarifies that the "set in advance" provision for compensation in an initial arrangement is a deeming provision and is optional. It is unnecessary for the parties to reduce the compensation to writing before the furnishing of the items or services. Further, the terms of § 411.354(e)(i) apply to the initial arrangement, allowing parties up to 90 days to satisfy the writing and signature requirements of the applicable exception. This creates flexibility for physicians and providers to commence an arrangement and then memorialize the details later. Although CMS declined to provide specific terms for how parties can demonstrate compensation was set in advance, vit stated that, for example, records of a consistent rate of payment over the course o f an arrangement typically support such inference.

A significant change in the Final Rule is the deletion of the prohibition on modifying the formula during the term of the arrangement. When the Final Rule takes effect, parties will be able to modify compensation (or a formula for determining the compensation) at any time during the course of the arrangement provided the following conditions are met:

1. All requirements of an applicable exception in §§ 411.355 through 411.357 are met on the date the modification takes effect;

2. The modified compensation (or the formula for determining the modified compensation) is determined before the furnishing of the items or services for which the modified compensation is to be paid; and

3. Before furnishing the items or services for which the modified compensation is to be paid, the formula for the modified compensation is set forth in writing in sufficient detail so that it can be objectively verified.

Importantly, the Final Rule specifically provides that, unlike the initial arrangement, the parties do not have 90 days under § 411.354(e)(4) to reduce the modified compensation terms to writing, but notes that the documentation of the modified compensation need not be signed by the parties.

The amended arrangement must satisfy all of the requirements of the applicable exception. The Final Rule also reminds parties that even if modifications do not directly alter the compensation, they may still trigger the requirements described above if the changes are material to the compensation terms. For example, modifications that decrease a physician's schedule, but keep the same rate in place, may increase a physician's compensation above fair market value, which would not meet the requirements of the applicable exception. In contrast, modifications that do not alter compensation, such as a change in schedule from one day to another, do not trigger the requirements described above.

The Final Rule does not codify how parties may establish that a modified compensation arrangement was documented before the furnishing of the items or services, but states that there are many ways an arrangement may be documented. These include a collection of documents, informal communications via email or text, internal notes to file, similar payments between the parties from prior arrangements, generally applicable fee schedules or, where no formal generally applicable fee schedule exists, other documents showing a pattern of payments to or from other similarly situated physicians for the same or similar items or services. The Final Rule also provides that modifications do not have to remain in place for at least one year from the date of the amendment and there is no prohibition on the number of times the parties may modify the compensation.

Directed Referrals

If a physician's compensation under an employment relationship, personal service arrangement, or managed care contract is conditioned on the physician's referrals of designated health services (DHS) to a particular provider, practitioner, or supplier (known as directed referrals), the arrangement must meet certain requirements set forth in § 411.354(d)(4). The Final Rule makes three significant changes to directed referral requirements:

1. Any changes to the compensation (or formula for determining the compensation) must be made prospectively;

2. Deletion of the requirement that the payment does not take into account the volume or value of anticipated or required referrals; and

3. Regardless of whether the physician's compensation takes into account the volume or value of referrals by the physician, neither the existence of the compensation arrangement nor the amount of the compensation is contingent on the number or value of the physician's referrals to the particular provider.

Regarding item (2) above, CMS states that it no longer believes that compensation predicated on the physician making referrals of DHS to a particular provider should be evaluated for compliance with the volume or value standard. Therefore, the Final Rule removes this language from § 411.354(d)(4). The Final Rule also clarifies that a directed referral requirement will not trigger analysis for compliance with the volume or value standard at § 411.354(d)(5) (described below).

Regarding item (3) above, neither the compensation arrangement nor the amount of the compensation may be contingent on the number or value of the physician's referrals to the particular provider. However, the Final Rule includes specific language that the physician may be required to refer an established percentage or ratio of the physician's referrals to a particular provider. The Final Rule does not state if any percentage or ratio is too high and, in an example, stated that an arrangement that required 90% of patients to be referred to a particular provider was permissible.

CMS explains that when a physician will receive no future compensation if s/he fails to refer as required, or if the amount of the compensation is tied to the physician's referral to a particular provider, there is a risk of program or patient abuse. CMS provides the following examples of arrangements that would be impermissible because they are contingent on the number or value of referrals: (i) if a hospital increases the physician's compensation in the renewal term only if the physician made a targeted number of referrals for DHS to the hospital in the current term; (ii) if the hospital refuses to renew (or terminates in the current term) unless the value of the physician's referrals generate sufficient profit to the hospital; or (iii) if the compensation arrangement would be terminated if the physician failed to refer a sufficient number of patients for DHS or the value of the physician's referrals failed to achieve the established target (however, if the established target was a percentage of referrals, it would not be prohibited).

Additionally, the Final Rule makes compliance with § 411.354(d)(4) a requirement to meet the following exceptions if directed referrals are part of the arrangement: § 411.355(e) (academic medical centers), and §§ 411.357(c) (bona fide employment relationships), (d)(1) (personal service arrangements), (d)(2) (physician incentive plan), (h) (group practice arrangements with a hospital), (l) (fair market value compensation), (p) (indirect compensation

arrangements), and (z) (limited remuneration to a physician).

Compensation that Takes into Account the Volume or Value of Referrals or Other Business Generated

Many exceptions under the Stark Law require that compensation not take into account the volume or value of referrals or other business generated between the parties (known as the "volume or value standard" and the "other business generated standard," respectively). The Final Rule adds a new clause at § 411.354(d)(5) to provide an objective test for determining whether arrangements will violate these standards, which CMS hopes will reduce confusion among providers. The new clause provides, in sum, that compensation from an entity furnishing DHS to a physician (or immediate family member of the physician) takes into account the volume or value of referrals, or other business generated, only if the formula used to calculate the compensation includes the physician's referrals to the entity, or other business generated by the physician for the entity, as a variable, resulting in an increase or decrease in the compensation that positively correlates with the number or value of the physician's referrals to, or the generation of other business for, the entity. The clause also provides that a positive correlation between two variables exists when one variable decreases as the other variable decreases, or one variable increases as the other variable increases. For example, a positive correlation exists if a physician's compensation increases as the number of the physician's referrals to the entity increases, or if the physician's compensation decreases as the number of his or her referrals decreases.

The Final Rule clarifies that outside of the circumstances described in § 411.354(d)(5), compensation will not be considered to take into account the volume or value of referrals or other business generated between the parties. If the mathematical calculation does determine that the compensation takes into account the volume or value of referrals, that determination is final—parties may not then apply the special rules at § 411.354(d)(2) (unit-based compensation and the volume or value standard) and (d)(3) (unit-based compensation and the other business generated standard) to obtain a different conclusion.

Additionally, the Final Rule explains that these special rules on compensation act like definitions and, other than several exceptions described below, the analysis of whether compensation takes into account the volume or value of referrals must be determined in accordance with § 411.354(d)(5). The exceptions for which § 411.354(d)(5) does not apply are: § 411.357(m) (medical staff incidental benefits), (s) (professional courtesy), (u) (community-wide health information systems), (v) (electronic prescribing items and services), (w) (electronic health records items and services), and (bb) (cybersecurity technology and related services).

The Final Rule's changes to the special rules on compensation set forth in § 411.354(d)(4) and (d)(5) will be helpful to physicians and other health care providers and suppliers in structuring compensation arrangements, without fear that failure to set compensation in advance of an initial arrangement, needing to modify compensation during an arrangement, or an incorrect application of the volume of value standard will violate the Stark Law. These changes take effect on January 19, 2021.


hermo

Stark Law Fair Market Value Compensation Exception Expanded to Cover Office Space and Equipment Leases and Clarifies Writing Requirements

In its first significant Stark Law rulemaking since 2015, the Centers for Medicare and Medicaid Services (CMS) recently issued a new final rule (Final Rule) intending to provide physicians and designated health services (DHS) entities with additional flexibility in complying with the law's stringent requirements.

Importantly, the Final Rule provides physicians and DHS entities with more flexibility and clarity regarding the fair market value (FMV) compensation exception, including by extending the scope of the exception to include office space and equipment leases. This update highlights major changes to the FMV compensation exception and provides an overview of the updated requirements.

Enhanced Flexibility for Office Space and Equipment Leases

The Final Rule removes the original FMV compensation exception's exclusion of office rental space and clarifies that the exception applies to both office space and equipment leases. Significantly, this not only offers entities another option for covering arrangements involving office space and equipment rentals but unlike the office space and equipment rental exceptions at 42 CFR Section 411.357(a) and (b) (which require that the office space and equipment be used exclusively by the lessor, subject to specified exceptions), the FMV compensation exception still does not have an exclusive use requirement. The FMV compensation exception also does not require a one-year term, offering even greater flexibility for shorter-term arrangements. This option may be particularly beneficial to providers in rural areas, where a shorter-term lease could meet community needs, such as relocating a physician to meet facility demands. Laboratories temporarily leasing space from physicians for specimen collections while a permanent space is constructed or renovated may also find the expanded exception helpful.

Notably, the FMV compensation exception is the only regulatory exception where CMS maintained in the Final Rule the mandate that the arrangement not violate the anti-kickback statute because, as CMS explained, it is a crucial safeguard against patient and program abuse. The explicit prohibition against violating the anti-kickback statute substitutes for certain statutory exception requirements that were omitted from this regulatory exception, including the exclusive use requirement in the case of renting office space and equipment.

Clarified Writing Requirements

Another significant change to the FMV compensation exception is CMS making the writing requirements more explicit. Although the substantive writing requirements did not themselves change, they were modified to clarify the requirement. Under the Final Rule, the signed writing required by the exception must specify:

- The items, services, office space, or equipment covered by the arrangement;
- The compensation to be provided; and
- The timeframe.

These requirements are consistent with the basic requirements for other exceptions that require signed, written agreements.

Updated Fair Market Value Compensation Exception Requirements (42 CFR Section 411.357(l))

DHS entities and physicians may use the updated FMV compensation exception to protect arrangements, including the payment of compensation for items or services or the leasing of office space or equipment, if the following requirements are met:

- **Writing:** The arrangement must be memorialized in a signed writing meeting the requirements described above.

- **Time Frame:** The arrangement may be for any time period and may contain a termination clause. The arrangement may be renewed without limit as long as the terms of the arrangement, the compensation, and the items, services, office space, or equipment covered remain unchanged. During the course of one year, the parties may only enter into one arrangement for the same items, services, office space, or equipment (unless the arrangement meets the conditions of paragraph (z), regarding limited remuneration to a physician).

- **Compensation:** The compensation provided under the arrangement must be set in advance, **be consistent with fair market value**, and must not take into account the referring physician's volume or value of referrals or other business generated. If the compensation is for renting office space or equipment, it may not be based on either (i) a percentage of the revenue attributed to the services or business performed in the office space or using the equipment, or (ii) service rental charges per unit, to the extent such charges reflect services rendered to patients referred by the lessor to the lessee.

- **Commercial Reasonableness:** The arrangement must be commercially reasonable, even if there were no referrals made between the parties.

- **Compliance with Other Laws:** The arrangement must not violate the anti-kickback statute. Also, the services provided under the arrangement must not involve counseling or promoting a business arrangement, or other illegal activity.

- **Remuneration Conditioned on Directed Referrals:** If the arrangement involves remuneration to a physician or group of physicians and is conditioned on referrals to a specific provider, practitioner, or supplier, it must meet the requirements of Section 411.354(d)(4), regarding directed referrals.

The updated FMV compensation exception became effective on January 19, 2021. DHS entities should review the changes and reassess their arrangements with physicians that rely on the FMV compensation exception to ensure the arrangements remain compliant. DHS entities also should consider whether they can benefit from the rule's new efficiencies related to office space and equipment leases, particularly with respect to short-term arrangements.

New Stark Exception Provides Additional Flexibility for Limited Financial Arrangements With Physicians

As part of its recent rulemaking process, the Centers for Medicare and Medicaid Services (CMS) finalized a new exception to the Physician Self-Referral Law (the Stark Law) to protect arrangements where limited remuneration is provided to a physician in exchange for items or services provided by the physician (the Limited Remuneration Exception).

View the finalized new exception.

CMS indicated that the new exception is due, in part, to the agency's review of numerous arrangements submitted for self-disclosure through CMS's self-referral disclosure protocol (SRDP).

Based on its review of the SRDP submissions, CMS concluded that there are arrangements – for example, short-term medical director arrangements - where limited remuneration is provided for needed items or services, but where the arrangement does not otherwise fit into an existing exception (for example, due to a failure to have a signed, written agreement memorializing the arrangement). The Limited Remuneration Exception will provide hospitals and other providers additional flexibility when entering into short-term arrangements with physicians. By availing themselves of the new exception, providers may also be able to avoid disclosing previously non-compliant physician relationships through the SRDP.

Requirements for the Limited Remuneration Exception

In finalizing the Limited Remuneration Exception, CMS determined that arrangements meeting the following requirements would not pose a risk of program or patient abuse and thus should be protected by the exception:

- The arrangement is for items or services actually provided by the physician;
- The amount of the remuneration provided to the physician is limited to an annual aggregate limit of $5,000, as adjusted annually for inflation;
- The arrangement is commercially reasonable;
- The remuneration is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician; and
- The remuneration does not exceed fair market value for the items or services.

Notably, the exception protects arrangements that are not set forth in a written agreement and arrangements where the remuneration is not set in advance. These are both common requirements for already existing exceptions, and prior to the Limited Remuneration Exception, a party's failure to meet them would have caused an arrangement to fall out of compliance. This would violate the law or necessitate disclosure through the SRDP. The Limited Remuneration Exception also protects payments to physicians where the physician provides the item or service through: (1) an employee hired for the purpose of performing the service, (2) a wholly-owned entity, or (3) a locum tenens physician.

Depending on the type of arrangement the Limited Remuneration Exception is being used to protect, there may be additional requirements that apply. First, if the arrangement requires a physician to refer patients to a particular provider, the arrangement must also comply with the special rules on compensation tied to referrals set forth in 42 C.F.R. § 411.354(d)(4).

Additionally, to the extent the Limited Remuneration Exception is applied to protect short-term leases for the use of office space or equipment, the compensation cannot be determined using a formula based on: (1) a percentage of revenue earned, billed, or collected while

using the space or equipment; or (2) per-unit of service fees that are not time-based (for example, based on "per-click" or "per-use"). These restrictions are similar to the restrictions on compensation formulas in the exceptions for indirect compensation and timeshare arrangements.

Finally, the Limited Remuneration Exception protects the first $5,000 paid to a physician by a designated health services entity (DHS entity), such as a hospital, in a calendar year. Therefore, if a DHS entity made payments up to $5000 to a physician through March 30th of one year, the hospital would be prohibited from making any additional payments to the physician during that calendar year unless the payments were protected by another Stark Law exception.

Applicability to Physician Organizations and Their Members

In certain instances, the compensation payments may apply towards the $5,000 limitation for more than one physician. Where remuneration is paid from a DHS entity directly to a physician, the compensation will apply towards that physician's $5,000 limit. However, when the remuneration is paid from a DHS entity to a physician organization (for example, a group practice), then the arrangement must be analyzed to determine whether the remuneration applies to the $5,000 limit of each of the physicians who "stand-in-the-shoes" of the physician organization (*i.e.*, all of the physician-owners), or to the $5,000 limit of a specific physician who is part of the physician organization.

Whether the compensation applies to one physician or to all physicians who stand-in-the-shoes of the physician organization will depend on the facts and circumstances of the arrangement. An analysis of the facts and circumstances may include, whether: (1) a specific physician provides the items or services under the arrangement (as opposed to multiple employees or physicians at the physician organization), (2) the items or services are owned by an individual physician, rather than the organization, and (3) the payments are made directly to an individual physician rather than the physician organization, and if payments are made to the organization, whether the organization functions purely as a middleman passing all payments to the physician providing the services.

When the analysis demonstrates that payments were made to the organization, rather than directly to a physician, the compensation will count towards the $5,000 limit of each physician required to stand-in-the-shoes of the organization.

The Benefits and Risks of the Limited Remuneration Exception

As CMS noted in the Final Rule, the Limited Remuneration Exception may help protect arrangements that traditionally have failed to meet existing exceptions, necessitating self-disclosure through the SRDP. For example, if a hospital needed a physician to provide emergency on-call services, but the parties did not have an opportunity to enter into a signed written agreement before the physician began providing the services, the Limited Remuneration Exception would protect the first $5,000 in payments to the physician. In the past, the hospital was required to execute a written agreement with the physician before making the payments, which could have been difficult in the case of an emergency.

Importantly, the Limited Remuneration Exception can be used in conjunction with other Stark Law exceptions in two ways. First, where an entity has multiple arrangements with a physician, and where the compensation for one of the services is protected by a different exception, the compensation that is otherwise protected by an exception does not count towards the $5,000. For example – if a hospital has an on-call arrangement with a physician that meets the requirements of the personal services exception and a second "supervision" agreement on a periodic basis that does not meet an existing exception, the first $5,000 paid to the physician under the supervision agreement could be protected by the Limited Remuneration Exception and payments under the on-call arrangement would not count towards the $5,000 limit. However, if a DHS entity has multiple undocumented, unsigned arrangements with the same physician, all of the arrangements would be considered a "single compensation arrangement" and the aggregate remuneration for all arrangements during the calendar year could not exceed the $5,000 limitation. To the extent the total compensation paid under the arrangements exceeded the maximum permitted amount, none of the arrangements would be protected.

The Limited Remuneration Exception can also be used in conjunction with another exception to protect an arrangement during the course of the arrangement. For example, if the physician receives $4,000 in compensation for medical director services before a signed, written agreement is put in place, the Limited Remuneration Exception can be used to protect the $4,000. Once the signed, written agreement is in place, the arrangement is then fully protected by the personal services exception.

Notably, CMS also explicitly modified exceptions to the personal services and fair market value exceptions so that they can be used with the Limited Remuneration Exception, primarily by clarifying that: (1) arrangements that meet the Limited Remuneration Exception do not have to be included in the list of arrangements (or otherwise cross-referenced) maintained for compliance with the personal services exception; and (2) the fair market value exception requirement that states that parties may only enter into one arrangement for the same items or services during the course of a year ***does not*** apply to arrangements that meet the Limited Remuneration Exception, thus permitting parties to use both exceptions, as necessary, to protect an arrangement for the same items or services during a calendar year.

While there are numerous benefits to the Limited Remuneration

Exception, including protecting arrangements with physicians that previously would not have met a Stark Law exception, providers relying on the Limited Remuneration Exception must carefully track the remuneration it pays to physicians. Once the $5,000 limit for a physician is met, the payments from the DHS entity to the physician must fall within another Stark Law exception or the parties will risk violating the law. In many instances, by taking a few additional steps, including memorializing the arrangement in a signed, written agreement, the parties to the arrangement will be able to use the personal services exception to protect the arrangement. When entering into short-term or otherwise limited arrangements with physicians, DHS entities should carefully consider their long-term goals regarding the arrangement and take necessary steps to ensure compliance with the Stark Law requirements throughout the arrangement. This includes converting arrangements that initially comply with the Limited Remuneration Exception into arrangements that fit the requirements of other applicable exceptions, as necessary.


12018150

Changes to Stark and Anti-Kickback Regulations Address Technology Advances, Tighten Rules for EHR Contributions, and Promote Cybersecurity

Fraud and abuse regulations have been adapted to meet today's technology for electronic data, promoting cooperation among health care providers for the exchange of health information and the protection of such information from cyberattacks.

The final rule published in the December 2, 2020 Federal Register (the Final Rule(s)) updates the existing Stark Law exceptions and AKS safe harbors to address the evolution of technology, provide for greater cybersecurity, and integrate the 21st Century Cures Act provisions related to information blocking and certifications of EHR by the Office of the National Coordinator (ONC). Although most of the changes provide for more flexibility and clarity as it relates to the donation of EHR and Cybersecurity assistance to providers, donors will have stricter requirements to meet with respect to satisfying the mandatory monetary contribution recipients must pay for EHR they receive.

Key Definition Changes

CMS and OIG initially proposed to change the definition of EHR to align with the Cures Act definition for "electronic health information." However, in the Final Rule, the agencies decided to retain the definition of EHR to mean "the consumer health status information in computer processable form used for the clinical diagnosis and treatment for a broad array of clinical conditions." The decision to keep this definition was based upon a concern that the proposed definition might be interpreted to expand the scope of the EHR exception. This was not the intention, and so the proposed change to the definition was withdrawn. The decision not to change the EHR definition re-enforces the concept that donated EHR software and services are for clinical support in the diagnosis and treatment of patients.

An important element of EHR eligible for donation under the exception and safe harbor is that it provides for interoperability to allow full access, secure exchange, and use of electronically accessible health information between other health information technologies. The definitions essentially remain the same as in prior versions of the regulations except that the revised definition drops the qualification "without special effort" on the part of the EHR user. The other qualification that prohibits information blocking is amended to coincide with the Cures Act that addresses both information blocking and interoperability certification by the ONC National Coordinator.

Additionally, definitions for 'Cybersecurity' were added to the Stark Law and AKS regulations to mean "the process of protecting information by preventing, detecting, and responding to cyberattacks." The new regulations expand protection for cybersecurity safeguards in EHR software and services. However, the HHS and OIG distinguished EHR and Cybersecurity as separate exceptions and safe harbors in the Final Rule.

The EHR Stark Law Exception and AKS Safe Harbor

Some of the requirements set forth in the prior version of the AKS safe harbor remain the same. However, the Final Rules incorporate the same requirement in the Stark Law exception and makes several notable changes.

The requirement that the recipient of donated EHR must contribute at least fifteen percent (15%) of the cost of the EHR is in both rules. However, the new rules clarify that the contribution requirement applies to subsequent donations of EHR, not just the initial donation, thereby precluding a donor from swapping out EHR software and services with no additional cost to the recipient. In addition, the new rules specifically prohibit the donor to finance physician payments or otherwise loan funds for physician recipients to use for their mandated EHR contributions.

Other changes include:

— Clarifies that EHR is deemed to be interoperable if, at the time it is donated, the EHR is

certified by the ONC National Coordinator.

- The prohibition concerning "information-blocking" adopts and references the Cures Act requirements.
- The relevant Stark Law exception removes the requirement that the arrangement must not violate AKS.
- The rule will not expire on a designated date with the elimination of the sunset provision previously set for December 31, 2021.

The Cybersecurity Stark Law Exception and AKS Safe Harbor

The Final Rules create a new Stark Law exception and AKS safe harbor for non-monetary donations of cybersecurity technology and related services that is necessary and predominantly used to create or sustain effective cybersecurity. If the cybersecurity functions are integrated into EHR, then the EHR exception and safe harbor apply. The benefits of the Cybersecurity exception and safe harbor is that it does not preclude the donation of hardware technology and does not require a financial contribution by the recipient.

Incorporated in the new cybersecurity provisions are requirements common to other exceptions and safe harbors, specifically:

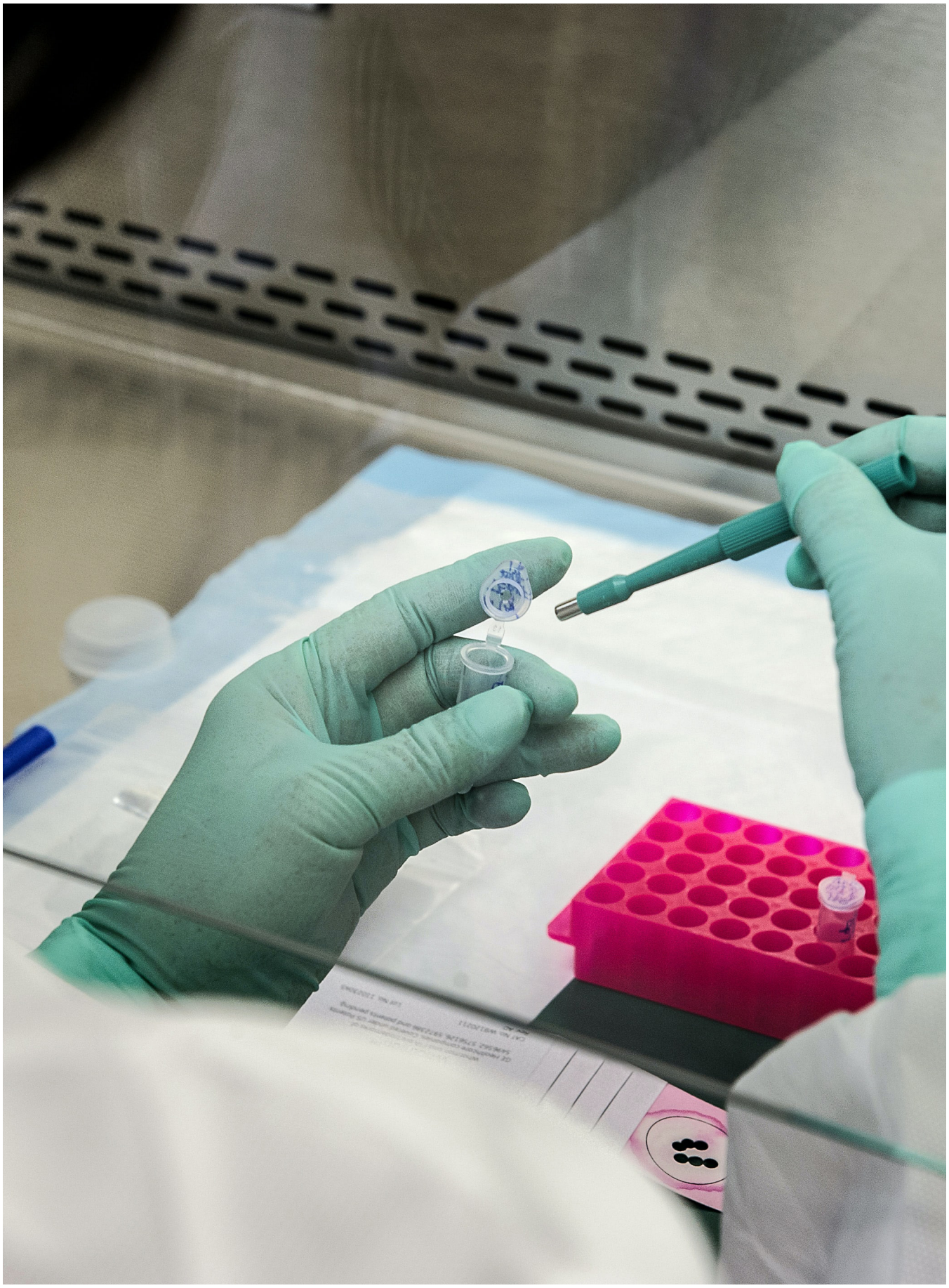
- The donation of technology is not tied to the value or volume of referrals or other business generated.
- There is no condition of future referrals or business between the parties tied to the donation.
- The arrangement for the cybersecurity donation is set forth in writing that identifies or generally describes the technology and services offered and any contribution made by the recipient.

The AKS safe harbor has an additional requirement that the donor does not shift the costs of the offered technology or services to any Federal health care program.

What This Means to You

The new regulations demonstrate the importance placed by the agencies on the security of health information exchange networks from cyberattacks. Hospitals, physicians and other providers will have broad flexibility in working together to establish a secure infrastructure for the exchange of electronic health data.

Changes to the EHR exception and safe harbor recognize the changes in technology and the interoperability of technology as well as the development of other laws that cover these issues. At the same time, changes in the definition of EHR and clarifications on the fifteen percent (15%) contribution requirement suggest the agencies want to tighten up possible loopholes in the EHR rules based upon a more liberal interpretation of the old regulations. The new rules will be particularly important to consider as EHR systems are updated or replaced.



New Safe Harbors Offer Opportunities for Innovative Arrangements, Including Digital Health

Recent updates to the federal Anti-Kickback Statute give providers additional flexibility to enter into innovative arrangements, but before doing so, providers must ensure they understand the safe harbor requirements necessary to protect those arrangements.

As part of its recent **updates to the Anti-Kickback Statute (AKS) rules** (the Final Rule), the US Department of Health and Human Services' Office of the Inspector General (OIG) issued several new regulatory safe harbors aimed at facilitating the shift to value-based care. These new safe harbors protect care coordination arrangements and arrangements promoting patient engagement and support (the Safe Harbors). Both of the Safe Harbors offer expanded opportunities for providers interested in entering into innovative arrangements, including arrangements aimed at increasing the use of digital health and telehealth. However, due to their complexities and limitations, providers contemplating such arrangements should carefully assess the applicable Safe Harbor requirements to ensure their arrangements are indeed "safe" from a compliance standpoint.

The Safe Harbors

While each of the Safe Harbors may be used to protect digital health arrangements, the purpose of the arrangement and the type of remuneratio n involved dictates which Safe Harbor applies to the arrangement. For instances where the arrangement involves the provision of remuneration between providers (for example, provision of equipment to assist in monitoring a patient population), the Care Coordination Safe Harbor may be applicable. In instances where the arrangement involves the provision of remuneration to a patient (for example, provision of a device or software to help ensure patient compliance with a medication regimen), the Patient Engagement Tools and Support Safe Harbor (Patient Engagement Safe Harbor) could apply.

Care Coordination Safe Harbor

The Care Coordination Safe Harbor is the most flexible of the value-based care arrangement safe harbors created by the Final Rule, as it does not require the arrangement or its participants to assume any level of financial risk. (A detailed description of the safe harbors protecting value-based arrangements where the participant assumes some level of financial risk, as well as an analysis of the requirements generally applicable to all value-based safe harbors can be found **here**) Instead, the Care Coordination Safe Harbor is intended to facilitate arrangements aimed at improving quality, health outcomes, and efficiency regardless of financial risk assumed by a participant and permits the exchange of in-kind remuneration (excluding cash and gift-cards) among value-based enterprise (VBE) participants (VBE participants) for coordinating and managing patient care activities.

The Care Coordination Safe Harbor generally requires:

- The remuneration, for example, the digital health device, to be predominantly used to engage in activities directly connected to the coordination of care and management of care for the population targeted by the value-based arrangement (the remuneration should not result in more than incidental benefits to patients outside of the target population);
- The arrangement does not induce the furnishing of medically unnecessary items or services or reduces or otherwise limits medically necessary items or services;
- The arrangement not limit the provider's (VBE participant's) ability to make decisions in the best interests of the patients;
- The arrangement not require a provider to direct referrals to another provider if the patient expresses a preference for a different provider, the patient's payor determines the provider, or directing such referral would otherwise conflict with applicable laws governing Medicare and Medicaid participation;
- The remuneration not be used to market items or services furnished by the VBE or its participants to patients or for patient recruitment activities;

— The arrangement must be commercially reasonable as with all value-based arrangements;

— Documentation describes: (1) the VBE and how the VBE participants will meet the VBE's value-based purposes; (2) the identified target population using legitimate and verifiable criteria prior to the commencement of the arrangement; (3) the specific arrangement(s), also including descriptions of the purposes of the activities covered by the arrangement(s), the specific activities to be undertaken by the parties, the term, the target population, the cost of the remuneration - either the offeror's cost and the methodology used to determine that cost or the fair market value of the remuneration, the recipient's contribution (percentage and amount), and the outcome or process measures used to determine the recipient's achievements in meeting the measures; and

— The offeror not take into account the volume or value of, or condition an offer of remuneration on, referrals of non-target population patients or business not covered by the arrangement.

To meet the Care Coordination Safe Harbor requirements, the recipient of the remuneration must also pay at least 15% of the offeror's cost for the in-kind remuneration either prior to receiving the remuneration for one-time costs or at reasonable regular intervals for ongoing costs. Additionally, the VBE must monitor and assess the arrangement to determine whether the parties are achieving expected outcomes on an annual basis or at least once during the term of the arrangement. If the VBE determines that an arrangement resulted in material deficiencies of quality of care or that the arrangement is unlikely to further the coordination or management of care for the target population, the parties to the arrangement must, within 60 days, either terminate the arrangement or develop and implement a corrective action plan to remedy the deficiencies.

In general, the Care Coordination Safe Harbor prohibits the following entities from participating as VBE participants and utilizing the protections of the Safe Harbor:

— Pharmaceutical manufacturers, distributors, or wholesalers;

— Pharmacy benefit managers;

— Laboratories;

— Compounding pharmacies;

— Device manufacturers;

— DMEPOS companies; and

— Medical device distributors and wholesalers.

As a result, many types of providers and suppliers who otherwise may be interested in providing digital health technologies or other in-kind remuneration to hospitals, physicians, or other practitioners as part of a value-based arrangement are precluded from doing so under the Care Coordination Safe Harbor. These entities could instead avail themselves of other safe harbor protections, however, most other safe harbors require fair market value compensation in exchange for the provision of items or services, including digital health technologies.

The Safe Harbor includes a pathway allowing device manufacturers that are not physician-owned and DMEPOS companies to exchange digital health technologies under the Safe Harbor as "limited technology participants" to the VBE. The OIG broadly defines "digital health technologies" to include "hardware, software, or services that electronically capture, transmit, aggregate, or analyze data and that are used for the purpose of coordinating and managing care." The term also includes "any internet or other connectivity service that is necessary and used to enable the operation of the item or service for that purpose." Thus, the arrangement could include subsidization of internet costs associated with the VBE arrangement provided the technology is "predominantly used" for the value-based activities as required by the Safe Harbor.

In addition to fulfilling the requirements listed above, limited technology participants cannot condition the exchange of the digital health technology on the recipient's exclusive use or minimum purchase of any items or services manufactured, distributed, or sold by the limited technology participant.

Providers who are considering availing themselves of the Care Coordination Safe Harbor should consider the following:

— Each stream of remuneration under the VBE must separately meet the requirements of the Safe Harbor.

— The OIG stated that if there is an enforcement action around a VBE, the government likely will analyze each arrangement with a remuneration stream separately but also consider the "totality of the arrangement" to assess potential AKS liability. Because VBEs are likely to include numerous arrangements and because the documentation requirements for the Care Coordination Safe Harbor are significant, it is important that providers entering into VBEs and utilizing the Safe Harbor maintain sufficient record-keeping processes to document and track each applicable arrangement.

— The remuneration exchanged under the Care Coordination Safe Harbor must be predominantly used to engage in the value-based activities for the target population. Where the remuneration is, for example, a health information technology tool, the parties to the arrangement must carefully assess whether the tool meets the "predominant use" requirement. For example, a tool that enables both remote patient monitoring and two-way telehealth interactions could satisfy the requirement if the technology

is used by the recipient to coordinate and manage care for the target population. However, if the tool also incorporated functions related to billing and collection of the services provided to the target population for purposes of the provider's financial operations, the tool likely would not meet the predominant use standard, and thus, the arrangement would not meet the Safe Harbor requirements. If the financial tool could be disabled, or the recipient otherwise paid fair market value for the financial tool, the arrangement may still meet the predominant use requirement. Regardless, the parties must carefully assess these concerns prior to availing themselves of the Care Coordination Safe Harbor.

Hospitals and other health care facilities interested in expanding the use of telehealth or digital health services in their service area, but who have had issues garnering interest from practitioners due to the costs associated with implementation of such programs, should consider whether the Care Coordination Safe Harbor will enable them to provide in-kind support to practitioners to expand their digital health programs as part of their value-based efforts. While the Safe Harbor has stringent requirements, it would allow the hospital or other facility to significantly offset the costs of program implementation for the practitioners, incentivizing practitioner involvement. And all parties involved in the arrangement will be well-positioned to take advantage of future shifts in reimbursement to value-based payments, having already established at least one value-based program.

Patient Engagement and Support Safe Harbor

For providers that are interested in providing in-kind tools and support to patients, including digital health technology, the Patient Engagement Safe Harbor offers a new means of protecting arrangements that promote population health. While the Safe Harbor does not contain the same stringent requirements as the other value-based care safe harbors, including the Care Coordination Safe Harbor, use of the Patient Engagement Safe Harbor requires the provider to be an eligible VBE participant. (A summary of the requirements for an eligible VBE participant can be found here) Thus, the Safe Harbor is not open for general use by all providers.

For eligible providers, the Patient Engagement Safe Harbor permits the provider to give patients in a target population technology, tools, and support valued at up to $500 annually to achieve identified health goals. The goals include adherence to a treatment or drug regimen, adherence to a follow-up care plan, prevention or management of a disease, or to ensure the patient's safety.

The tools and support permitted under the Safe Harbor must be: (1) related to care coordination and management, (2) recommended by a licensed practitioner, and (3) used to meet one of the identifiable health goals. The tools and support may include:

- Provision of in-kind transportation (for example, transit vouchers or ride shares organized by the VBE);
- Home modifications such as grab bars or air filters or purifiers, and other physical or structural modifications allowing the patient to live safely at home;
- Temporary housing for patients experiencing homelessness or for patients who are post-surgical discharge, but whose home is located at a distance from the hospital;
- Provision of broadband access to allow for remote patient monitoring or other virtual care;
- Grocery or meal delivery services;
- Exercise or fitness equipment and virtual exercise programs; and
- Incentives as part of mental health or recovery programs.

While the Patient Engagement Safe Harbor is limited to in-kind tools and support and generally prohibits the provision of cash or cash equivalents such as gift cards, in some circumstances, gift cards may be permissible. For example, gift cards that can be used like cash for any item or service are not permitted under the Safe Harbor. However, a gift card that is limited to certain items or services, such as a meal delivery service to address nutritional concerns or a ride-sharing service to address transportation issues would meet the in-kind requirement.

The OIG stated that the permitted tools and support list is not exhaustive and there may be other types of support that would fit within the Patient Engagement Safe Harbor. One purpose of the Safe Harbor is to provide flexibility for health care professionals to determine and recommend the tool or support that would best address a patient's social determinants of health and to promote coordination and management of patient care. For example, while not enumerated by the OIG, home "smart" technology aimed at ensuring patient safety likely would fit within the Safe Harbor. Similarly, a smartphone or software that facilitates telehealth services may be protected by the Safe Harbor.

However, the Patient Engagement Safe Harbor does not protect all tools that could be used to support patients. For example, tools and support of a "routine nature" such as ongoing rent or utility payments are unlikely to meet the requirements that the tools and supports (1) be related to care coordination and management, (2) are recommended by a licensed practitioner, and (3) related to one of the identifiable health goals, and thus the payments would not be protected under the Safe Harbor.

The Patient Engagement Safe Harbor, like the Care Coordination Harbor, excludes entities like pharmaceutical manufacturers, PBMs, and laboratories, from participating in VBE arrangements and thus using the Safe Harbor.

However, the Safe Harbor permits device manufacturers and medical supply companies that are not physician-owned to provide tools and support as long as the tools and support are digital health technologies. Notably, this carve-out is more limited than the Care Coordination Safe Harbor carve-out as DMEPOS companies are excluded from participation, regardless of the type of tools or supports provided. Examples of digital health technologies that could be provided under the Patient Engagement Safe Harbor include:

- Scales and blood pressure monitors that are used for purposes of remote patient monitoring and which track and transmit data to a provider;
- Software or applications that allow a patient's mobile device to monitor activity or other data; and
- Software or access to a platform that facilitates telehealth consults.

While the Safe Harbor requirements are not as stringent as the requirements for the value-based care safe harbors, the Patient Engagement Safe Harbor nevertheless has several enumerated requirements that must be met to fall within the protections of the Safe Harbor, including:

- The patient must be a member of the target population under the VBE (for example, the VBE could develop an initiative to make tools or support available to patients over the age of 65 with high blood pressure) and the target population cannot be defined by payor (all patients within the population must be eligible for the tools or support, regardless of payor), though the population can be defined by age;
- The tool or support is not funded or contributed by a party that is excluded from being a VBE participant and using the Safe Harbor, or by a VBE participant who is not a party to the arrangement;
- The VBE participant does not exchange or use the tools or supports to market other reimbursable items or services or for patient recruitment purposes (for example, advertising that patients may be eligible to receive a smartphone if they use a particular provider); and
- Maintaining records for at least 6 years that establish that the patient tool or support was distributed in accordance with the requirements of the Safe Harbor.

VBE participants interested in using the Patient Engagement Safe Harbor should:

- Ensure they have identified an appropriate target population of patients who are eligible for the tools and support;
- Confirm the tools and support being provided are tied to patient care coordination and management and will help the patients achieve an identifiable health goal; and
- Ensure they are maintaining adequate records to reflect compliance with the Safe Harbor, including records documenting the target population, how the tools and support are tied to patient care coordination, and the patients who actually receive the support as part of the target population.

Conclusion

These new Safe Harbors offer providers interested in instituting new value-based care programs, or expanding existing programs, additional protections when entering into innovative arrangements. However, the Safe Harbors are complex, and while failure to meet all requirements of a Safe Harbor does not automatically result in AKS liability, innovative arrangements that fail to meet the elements of the applicable Safe Harbor likely have a higher risk of enforcement due to the probable nexus between the remuneration and referrals. Providers seeking to avail themselves of a Safe Harbor's protections should ensure they have sufficient processes in place to meet all of the Safe Harbor's requirements, including both maintaining sufficient documentation and appropriately defining the target population of the value-based arrangement. Providers should also ensure that the party offering to provide support under the value-based arrangement is permitted to do so under the applicable Safe Harbor.

Flagyl
Nexcomp Flow
voco
Cuxhaven • Germany
4.5g

About Us

Founded in 1942, Arent Fox is internationally recognized in core practice areas where business and the law intersect. With more than 430 lawyers and professionals, the firm provides strategic legal counsel and multidisciplinary solutions to a global roster of corporations, governments, and trade associations.

BOSTON
LOS ANGELES
NEW YORK
SAN FRANCISCO
WASHINGTON, DC

arentfox.com